K003570

JUN - 6 2001

**510(k) Summary**

General Information

| | |
|---|---|
| Classification | Class II |
| Trade Name | Solera Bacchus Thrombectomy Catheter (BTC) |
| Submitter | Bacchus Vascular, Inc.<br>3110 Coronado Drive<br>Santa Clara, CA 95054<br><br>408-980-8300 |
| Contact | Robert A. Clark, Jr.<br>Vice President & General Manager |

Intended Use

The Solera Bacchus Thrombectomy Catheter permits mechanical thrombectomy of synthetic hemodialysis grafts.

Predicate Devices

Arrow-Trerotola™ Over-the-Wire Percutaneous Thromoblytic Device (PTD)™
K990829
Manufactured by Arrow International, Inc.

Device Description

The Solera Bacchus Thrombectomy Catheter (BTC) consists of a 7-French over the wire catheter with an helical screw drive shaft connected to a macerator inside a graft protection basket. The macerator spins within the graft protection basket at approximately 3500 RPM from power provided by an integral Motor Drive Unit (MDU).

Materials

All materials used in the manufacture of the Solera BTC are suitable for this use and have been used in numerous previously cleared products.

Testing

The following testing was conducted to ensure the Solera BTC met all specifications:

- Tensile Tests
- Torque to Fail
- Life Tests
- Electrical Safety Testing
- Biocompatibility
- Sterilization Validation

The results of the above tests demonstrated that the device is as safe & effective as the legally marketed predicate device. All components, subassemblies, and/or full devices met the required specifications for the above tests.

Summary of Substantial Equivalence

The Solera BTC is equivalent to the predicate products from Arrow International, Inc.. The indications for use, basic overall function, methods of manufacturing, and materials used are substantially equivalent. Bacchus Vascular, Inc. believes the Solera BTC is substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2001

Ms. Marybeth Gamber
Regulatory Associate
Bacchus Vascular, Inc.
3110 Coronado Drive
Santa Clara, CA 95054

Re: K003570
Trade Name: Bacchus Thrombectomy Catheter
Regulation Number: 870.4875
Regulatory Class: II (two)
Product Code: MCW
Dated: March 28, 2001
Received: March 30, 2001

Dear Ms. Gamber:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might

have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

| | |
|---|---|
| 510(k) Number (if known): | K003570 |
| Device Name: | Solera™ Bacchus™ Thrombectomy Catheter (BTC) |
| Indications for Use: | The Solera Bacchus Thrombectomy Catheter permits mechanical thrombectomy of synthetic hemodialysis grafts. |

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003570

Prescription Use ____ OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)